IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-286 (GMS)
BARR LABORATORIES, INC.	)	
Defendant.	)	

BARR LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Jury Trial Demanded

Defendant Barr Laboratories, Inc. ("Barr"), by and through the undersigned attorneys, answers the Complaint of Plaintiffs Aventis Pharmaceuticals Inc. ("Aventis") and Sanofi-Aventis US LLC, ("Sanofi-Aventis" and, together with Aventis, "Plaintiffs"), as follows:

COMPLAINT:

1. Aventis Pharmaceuticals Inc., a subsidiary of Sanofi-Aventis SA, is a corporation organized and existing under the laws of Delaware, having its principal place of business at 300 Sommerset Corporate Boulevard, Bridgewater, New Jersey 08807.

ANSWER: Admitted, on information and belief.

COMPLAINT:

2. Sanofi-Aventis US LLC, a subsidiary of Sanofi-Aventis SA, is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 300 Sommerset Corporate Boulevard, Bridgewater, New Jersey 08807.

ANSWER: Admitted, on information and belief.

COMPLAINT:

3. On information and belief, Barr is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2 Quaker Road, Pomona, New York 10970.

ANSWER: Admitted.

Nature of the Action

COMPLAINT:

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*

ANSWER: Barr admits that Plaintiffs' Complaint is for patent infringement but denies that Plaintiffs are entitled to such relief.

Jurisdiction and Venue

COMPLAINT:

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Barr admits that this Court has subject matter jurisdiction over Aventis's infringement claims on the patents-in-suit. Barr denies the remaining allegations of paragraph 5.

COMPLAINT:

6. This Court has personal jurisdiction over Barr by virtue of its existence as a corporation organized and existing under the laws of Delaware and, *inter alia,* its other presence in Delaware and its continuous and systematic contacts with Delaware.

ANSWER: Admitted.

COMPLAINT:

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Admitted.

The Patents

COMPLAINT:

8. United States Patent No. 5,976,573 ("the '573 patent") duly and legally issued on November 2, 1999, to inventor Soo-Il Kim. The '573 patent was assigned to Rorer Pharmaceutical Products Inc., a predecessor-in-interest to Aventis. By assignment, through a chain of predecessors-in-interest, Aventis is the present owner of the '573 patent. At all times from the issuance of the '573 patent to the present, Aventis or one of its predecessors-in-interest has owned the '573 patent. A true and correct copy of the '573 patent is attached hereto as Exhibit 1.

ANSWER: Barr admits that the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,976,573 ("the '573 patent") on November 2, 1999, and that Soo-Il Kim is listed as the inventor on the face of the '573 patent. Barr further admits that Rorer Pharmaceutical Products Inc. is listed as the assignee on the face of the '573 patent and that the PTO currently lists Aventis Pharmaceuticals Inc. as the assignee. Barr denies that the '573 patent was duly and legally issued. Barr is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8, and therefore denies the same.

COMPLAINT:

9. United States Patent No. 6,143,329 ("the '329 patent") duly and legally issued on November 7, 2000, to inventor Soo-Il Kim. The '329 patent was assigned to Rorer Pharmaceutical Products Inc., a predecessor-in-interest to Aventis. By assignment, through a chain of predecessors-in-interest, Aventis is the present owner of the '329 patent. At all times from the issuance of the '329 patent to the present, Aventis or one of its predecessors-in-interest has owned the '329 patent. A true and correct copy of the '329 patent is attached hereto as Exhibit 2.

ANSWER: Barr admits that the PTO issued U.S. Patent No. 6,143,329 ("the '329 patent") on November 7, 2000, and that Soo-Il Kim is listed as the inventor on the face of the '329 patent. Barr further admits that Rorer Pharmaceutical Products Inc. is listed as the assignee on the face of the '329 patent and that the PTO currently lists Aventis Pharmaceuticals Inc. as the assignee. Barr denies that the '329 patent was duly and legally issued. Barr is

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9, and therefore denies the same.

Acts Giving Rise to this Action

COMPLAINT:

10. Aventis sells drug products containing triamicinolone acetonide in the United States under the trademark NASACORT AQ®, pursuant to NDA 20-468 held by Sanofi-Aventis US LLC.

ANSWER: Barr admits that FDA lists Sanofi-Aventis as the holder of NDA No. 20-468, relating to NASACORT AQ®. Barr is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10, and therefore denies the same.

COMPLAINT:

11. By letter dated March 20, 2006 ("Notification Letter"), Barr notified Aventis that Barr had submitted Abbreviated New Drug Application ("ANDA") 78-104 to the FDA under Section 505(j)(l) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(l)), seeking approval to engage in the commercial manufacture, use and sale of an aqueous nasal spray that will include 0.055 µg/spray of active triamcinolone acetonide (Barr's "ANDA Product"). On information and belief, Barr stated in its ANDA that its ANDA Product is bioequivalent to Aventis' NASACORT AQ® product.

ANSWER: Barr admits that it notified Aventis by letter dated March 20, 2006 that it submitted to FDA ANDA No. 78-104 under 21 U.S.C. § 355(j)(1) and 355(j)(2)(A). Barr admits the remaining allegations of paragraph 11.

COMPLAINT:

12. As stated in the Notification Letter, Barr's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Barr's ANDA Product prior to the expiration of the '573 and '329 patents, each of which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" ("the Orange Book") as being applicable to Aventis's NASACORT AQ® product. On information and belief, Barr intends to engage in the commercial manufacture, use and sale of its ANDA Product promptly upon receiving FDA approval to do so.

ANSWER: Barr admits that it seeks FDA approval of its ANDA to manufacture, use and sell a generic triamcinolone acetonide aqueous nasal spray, 0.055 μg/spray, product. Barr further admits that the '573 and '329 patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluation (the "Orange Book") in connection with NASACORT AQ®, and that it has submitted to FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") for each of the '573 and '329 patents, seeking FDA approval of its product prior to the expiration of those patents. Barr denies the remaining allegations of paragraph 12.

COMPLAINT:

13. In its Notification Letter, Barr notified Aventis that its ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that in Barr's opinion, the '573 and '329 patents are invalid, unenforceable or will not be infringed by the commercial manufacture, use, or sale of Barr's ANDA Product.

ANSWER: Admitted.

COMPLAINT:

14. Barr's filing of its ANDA to obtain approval to engage in the commercial manufacture, use and sale of its ANDA Product, prior to the expiration of the '573 and '329 patents, constitutes infringement of one or more of the claims of each of these patents under 35 U.S.C. § 271(e)(2).

ANSWER: Barr admits that filing an ANDA containing a paragraph IV certification to an Orange Book listed patent vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Barr denies the remaining allegations of paragraph 14, including any implication that the product that is the subject of Barr's ANDA infringes any valid claim of the '573 or '329 patent.

COMPLAINT:

15. Defendants had notice of the '573 and the '329 patent at the time of their infringement. Defendants' infringement has been, and continues to be, willful and deliberate.

ANSWER: Denied.

COMPLAINT:

16. Plaintiffs will be substantially and irreparably damaged and harmed by Barr's infringement. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Second Affirmative Defense

This Court lacks subject matter jurisdiction under 35 U.S.C. § 281 over Sanofi-Aventis's patent infringement claims.

Third Affirmative Defense

The claims of the '573 and '329 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Fourth Affirmative Defense

The manufacture, use, or sale of Barr's ANDA product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '573 or '329 patent.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Jury Trial Demanded

For its counterclaims against Plaintiff Aventis Pharmaceuticals Inc. ("Aventis"), Defendant Barr Laboratories, Inc. ("Barr") states as follows:

Parties

1. On information and belief, Aventis is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Barr is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc, and is organized and existing under the laws of the State of Delaware, having its principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.

Background

A. FDA Approval Of New Brand-Name Drugs.

3. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

4. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

5. A NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

6. Upon approval of the NDA, FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications.

7. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

8. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

9. To receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

10. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

11. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12).

12. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

13. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

14. Patent holders have a significant strategic incentive to file suit within 45 days because doing so, regardless of merit, prevents FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

15. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, FDA will not approve the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringe, FDA may approve the ANDA. *Id.*

C. Barr's ANDA.

16. Barr filed an ANDA (No. 78-104) with FDA seeking generic approval for triamcinolone acetonide aqueous nasal spray, 0.055 µg/spray. The ANDA shows that Barr's ANDA product is bioequivalent to the product that is the subject of NDA No. 20-468, the holder of which FDA lists as Sanofi-Aventis US LLC ("Sanofi-Aventis" and, together with Aventis, "Plaintiffs").

17. Sanofi-Aventis listed U.S. Patent Nos. 5,976,573 ("the '573 patent") and 6,143,329 ("the '329 patent") in the Orange Book in connection with NDA No. 20-468.

18. Because Barr seeks FDA approval to market its ANDA product before expiration of the '573 and '329 patents, Barr's ANDA includes paragraph IV certifications to those patents.

19. On March 20, 2006, Barr sent to Plaintiffs a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the '573 and '329 patents are invalid, unenforceable, and/or not infringed by Barr's ANDA product.

20. On May 2, 2006, Plaintiffs filed their patent infringement lawsuit against Barr, alleging that Barr's ANDA product would infringe the '573 and '329 patents.

Jurisdiction and Venue

21. Barr realleges and incorporates by reference the allegations of paragraphs 1-20.

22. Present, genuine and justiciable controversies exist between Aventis and Barr regarding the '573 and '329 patents.

23. Subject matter jurisdiction over these counterclaims exists under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

24. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

Counterclaim I
Declaration of Invalidity of the '573 Patent

25. Barr realleges and incorporates by reference the allegations of paragraphs 1-24.

26. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '573 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

27. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the validity of claims of the '573 patent.

28. Claims of the '573 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

29. Barr is entitled to a declaration that claims of the '573 patent are invalid.

Counterclaim II
Declaration of Non-Infringement of the '573 Patent

30. Barr realleges and incorporates by reference the allegations of paragraphs 1-29.

31. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '573 patent will not be infringed by the manufacture, use, or sale of the products described in Barr's ANDA No. 78-104.

32. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Barr's proposed ANDA product would infringe claims of the '573 patent.

33. The manufacture, use, or sale of Barr's ANDA products would not infringe claims of the '573 patent.

34. Barr is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '573 patent.

Counterclaim III
Declaration of Invalidity of the '329 Patent

35. Barr realleges and incorporates by reference the allegations of paragraphs 1-34.

36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '329 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

37. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the validity of claims of the '329 patent.

38. Claims of the '329 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

39. Barr is entitled to a declaration that claims of the '329 patent are invalid.

Counterclaim IV
Declaration of Non-Infringement of the '329 Patent

40. Barr realleges and incorporates by reference the allegations of paragraphs 1-39.

41. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '329 patent will not be infringed by the manufacture, use, or sale of the products described in Barr's ANDA No. 78-104.

42. A present, genuine, and justiciable controversy exists between Aventis and Barr regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Barr's proposed ANDA product would infringe claims of the '329 patent.

43. The manufacture, use, or sale of Barr's ANDA products would not infringe claims of the '329 patent.

44. Barr is entitled to a declaration that the manufacture, use, or sale of its ANDA products would not infringe claims of the '329 patent.

REQUEST FOR RELIEF

WHEREFORE, Defendant Barr Laboratories, Inc. respectfully requests that this Court enter a Judgment and Order in its favor and against Aventis Pharmaceuticals Inc. as follows:

(a) declaring that the claims of U.S. Patent No. 5,976,573 are invalid;

(b) declaring that Barr has not infringed and that Barr's manufacture, use, or sale of products covered by ANDA No. 78-104 would not infringe the claims of U.S. Patent No. 5,976,573;

(c) declaring that the claims of U.S. Patent No. 6,143,329 are invalid;

(d) declaring that Barr has not infringed and that Barr's manufacture, use, or sale of products covered by ANDA No. 78-104 would not infringe the claims of U.S. Patent No. 6,143,329;

(e) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Barr its attorneys' fees, costs, and expenses in this action; and

(f) awarding Barr any further and additional relief as the Court deems just and proper.

Dated: May 22, 2006

BARR LABORATORIES, INC.

By: _____

Josy W. Ingersoll (#1088)
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
jingersoll@ycst.com
Tele: (302) 571-6672
Fax: (302) 571-1253

George C. Lombardi
Maureen L. Rurka
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
Tele: (312) 558-5600
Fax: (312) 558-5700

Attorneys for Defendant Barr Laboratories, Inc.

CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that on May 22, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Steven J. Balick, Esquire
John G. Day, Esquire
Tiffany Geyer Lydon, Esquire
ASHBY & GEDDES
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801

I further certify that on May 22, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY FEDERAL EXPRESS

Paul H. Berghoff, Esquire
Joshua R. Rich, Esquire
Jeremy E. Noe , Esquire
Paul S. Tully, Esquire
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606

/Josy W. Ingersoll (#1088)